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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,719	10/20/99	MIYASHITA	M 10059-308(P2)

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EXAMINER

PADMANABHAN, K

ART UNIT	PAPER NUMBER
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1641

DATE MAILED

C
11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/420,719

Applicant(s)

MIYASHITA ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as **"means"** and **"said,"** **should be avoided**. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "proper" in claims 1 and 5 is a relative term which renders the claims indefinite. The term "proper" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "proper" in regards to the condition of the sample as in claim 1 and the pH of the sample in claim 5 is vague and indefinite, as it is unclear what this limitation encompasses.

5. The term "capable" in claim 5 is vague and indefinite, as it is unclear if the buffer solution adjusts the pH of the sample solution or not.

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6. The phrase "closest to a proper condition" in Claim 7 is vague and indefinite. The metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Pat. 5,262,305). Heller et al. disclose a biosensor including an interferant eliminating catalyst. The apparatus of the invention has an interferant eliminating layer, including a catalyst, wherein the catalyst is capable of oxidizing and thereby eliminating a plurality of interfering compounds from the sample before it reaches the sensor (col. 1). The catalyst mediates oxidation of an interferant in the presence of an oxidant to yield a non-interfering compound that does not interfere with the biosensor's function. In addition, the catalyst may be a natural enzyme (col. 4).

9. Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Foulds et al. (US Pat. 5,124,253). Foulds et al. disclose a device and method, wherein isozymes are employed to remove or inactivate endogenous alkaline phosphatase, thereby minimizing interference. In addition, the system also comprises a suitable buffer to alter the pH of the sample solution, often blood with a pH of 7.4, to an alkaline value suited to the enzyme of the test element (col. 4).

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10. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshioka et al. (US Pat. 5,229,282). Yoshioka et al. disclose a biosensor wherein the enzyme glucose oxidase oxidizes glucose in the sample liquid (cols. 4-5). In this case, it is inherently obvious that glucose can act as an interfering agent, and oxidation is necessary to prevent inaccurate reading when presented to the biosensor.

11. Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshioka et al. (US Pat. 5,192,415). Yoshioka et al. disclose a biosensor wherein the pH of the sample liquid is adjusted to the pH that provides the most stable enzyme activity. The pH is adjusted through the action of a buffering salt contained in a hydrogen ion concentration control layer. The enzyme of the device reacts with the interfering substance, thereby oxidizing and eliminating it.

12. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al. (US Pat. 4,431,507). Nankai et al. disclose a device in which an electrode is provided to electrochemically oxidize interfering materials in the sample solution. The enzyme of the electrode oxidizes interfering materials such as uric or ascorbic acid (col. 3).

13. Claims 1, 4, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bockowski (US Pat. 5,271,819). Bockowski et al. disclose a sensor electrode and a method for detecting selected characteristics in a sample solution. The reference discloses the use of absorbents, such as activated carbon, to remove specific contaminants or interferants from the sample solution (col. 3). The solution is then allowed to reach the biosensor.

14. Claims 1 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Amano et al. (US Pat. 5,385,830). Amano et al. disclose an apparatus comprising a heating trough where

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the sample and buffer are heated. The reference also discloses a reaction trough comprising a biosensor equipped pH meter, wherein the sample proceeds to the pH meter following a heating step (figure 2).

Conclusion

Claims 1-7 are rejected.

References: Ikeda et al., Henning et al., Nankai et al., Maley et al., Tanaka et al., Flaherty et al., Berry et al., Oh et al., Ollington et al., Gilmartin, DeFilippi, Cunningham, and Nelson are cited as art of particular interest for teaching various sensors and sample preparation devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4243 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

KP

October 30, 2000

Long Le

LONG V. LE
SUPERVISORY PATENT EXAMINER
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